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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,356	12/03/2007	Polly Gregor	D6547	7507

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	

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05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,356	GREGOR ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27 and 34-48* is/are pending in the application.

4a) Of the above claim(s) *26,27 and 34-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction/election requirement received on 4/23/10 has been entered. Applicant's election without traverse of Group III, claims 1-10 and 21-25, is acknowledged. Claims 1-10, 21-27, and 34-48 are pending in the instant application. Of these, claims 26-27, and 34-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/23/10. Claims 1-10 and 21-25 are currently under examination based on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4, 6, 8 and 9 as written recite that TEM8 "has a nucleic acid sequence of…" or "has an amino acid sequence .." 80% or 90% homologous to SEQ ID NOS 2, 3, or 5. However, the use of the indefinite article "a" or "an" renders these claims broad as any nucleic acid

sequence or amino acid sequence having one or more nucleotides in common with any of the recited SEQ ID NOS meets the limitation of these claims.

The specification does not provide sufficient written description for the genus of nucleic acid sequences which encode TEM8 or the genus of amino acid sequences of a TEM8 protein encompassed by the claims as written. The specification discloses that TEM8, which stands for tumor endothelial marker 8, is a marker protein expressed in colonic endothelial cells and in particular tumor vascular endothelial cells in human colon cancers. The specification also teaches that the human and mouse TEM8 nucleic acids sequences are known, and that the mouse sequences is 96% identical to the human sequence. However, the specification further teaches that the physiological function of TEM8 is unknown (specification, page 9, lines 13-14). Thus, there is no known assay to test whether any sequence which shares one, two or more nucleotides with the nucleic acid sequence of either the mouse or human TEM8 sequence actually encodes a TEM8 protein. Likewise, there is no known assay to test whether any amino acid sequence which only shares one, two or more amino acids with the amino acid sequence of mouse or human TEM8 protein, or even one with 80% or 90% homology with SEQ ID NOS 2, 3, or 5, shares any functional property with TEM8. In addition, the specification fails to provide any guidance as to structural domains or other sequence necessary for any functional activity of a TEM8 present in either the mouse or human TEM8 sequence such that sequences which meet the claim limitations can be identified by sequence information alone. Thus, aside from the human and mouse sequences disclosed in the specification, neither the specification nor the prior art provides the requisite written description for the genus of TEM8 sequences encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is claimed." (See page 1117). The instant specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may also be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the appellant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). The applicant has not provided any description or reduction to practice of any TEM8 nucleic acid or amino acid sequence other than human or mouse TEM8. Based on the teachings of the specification which states that the physiological function of TEM8 is unknown, and the lack of any description of essential functional domains or sequence which define a TEM8 nucleic acid or protein, the

skilled artisan cannot envision the detailed chemical structure of the genus of TEM8 nucleic acids or proteins encompassed by the claims. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. See *Fiers v. Revel,* 25 USPQ2d 1602 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016. Thus, for the reasons outlined above, the claims do not meet the requirements for written description under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/41787 (2001), hereafter referred to as Fikes et al., in view of US 2003/0148410 (2003), hereafter referred to as Berger et al. In regards to claims 4, 6, 8, and 9, please note that the claims as written recite that TEM8 "has a nucleic acid sequence of…" or "has an amino acid sequence ..". However, as discussed above, the use of the indefinite article "a" or "an" renders the claims broad as any nucleic acid sequence or amino acid sequence having one or more nucleotides in common with any of the recited SEQ ID NOS meets the limitation of these claims.

Fikes et al. teaches peptide epitope fragments of the tumor antigen Her2/neu and expression vectors encoding peptide epitope fragments of the tumor antigen Her2/neu, pharmaceutical compositions comprising the expression vectors, and methods of preventing/treating cancer by immunizing a mammal with expression vectors encoding Her2/neu (Fikes et al., pages 33-41, and 64-72). Fikes et al. further teaches that the expression vectors encoding Her2/neu can be combined with other nucleic acids encoding tumor associated antigens to modulate the anti-tumor immune response (Fikes et al., pages 38 and 67).

Berger et al. supplements Fikes et al. by teaching that nucleic acids encoding the TEM-8 protein can be used as vaccines to prevent or treat colon cancer (Berger et al., pages 6 and 30). Note that the TEM-8 protein disclosed by Berger et al. includes at least the amino acid sequence of SEQ ID NO:3 as claimed in claims 5 and 7. Berger et al. further teaches that the nucleic acid vaccines can be plasmids or liposome/vector complexes, that the vectors can be administered intravenously, subcutaneously, or intramuscularly, and that the TEM-8 vaccines can be administered in combination with other expression constructs encoding an immunomodulatory protein or tumor marker (Berger et al., paragraph 170, and page 30). Therefore, in view of the

teachings of Fikes et al. and Berger et al. that Her2/neu or TEM-8 nucleic acids can be used as vaccines to treat cancer, and the motivation provided by both Fikes et al. and Berger et al. for combining Her2/neu or TEM-8 therapy with other tumor markers/tumor associated antigens, it would have been *prima facie* obvious to combine the administration of an expression construct encoding Her2/neu with an expression construct encoding TEM-8 to induce anti-tumor immune responses with a reasonable expectation of success.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the new technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your

application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633